

## **REMARKS/ARGUMENTS**

Upon entry of the foregoing amendments, claims 1 to 6 and 9 to 17 will be pending in the present patent application. Claims 1, 2, 6 and 9 have been amended, without prejudice, to place them in better form. Claims 7 and 8 have been canceled, without prejudice. New claims 10 to 19 have been added. Support for the new claims is found at least in the specification at paragraphs [0017] to [0024] and [0054]. Applicant reserves the right to pursue subject matter that remains after the prosecution of the present application in a future continuing patent application, for example, a division.

### **Discussion of the Requirement**

The Action requires applicant to select one of the following three groups of allegedly patentably distinct inventions for examination.

- I. Claims 1 to 5 and 7, drawn to a topical pharmaceutical compositions;
- II. Claims 6 and 8, drawn to processes for preparing a composition;
- III. Claims 8 and 9, drawn to methods for treating hyperproliferative disorders.

Although applicant submits respectfully that the Requirement is improper, applicant elects provisionally the claims of Group I. The Action includes also a request that applicant provisionally elects a species of compound. In this regard, applicant elects the compound of formula I wherein R is ethyl, namely 6-[2-(2,5-dimethoxyphenyl)ethyl]-4-ethyl-quinazoline. Applicant requests respectfully reconsideration and withdrawal of the Requirement.

PCT Rule 13.1 states clearly that restriction is not required unless the inventions lack unity with regard to the common technical feature which is patentable over the prior art. Applicant submits respectfully that the common technical feature of the present invention is patentable over the prior art. Accordingly, the inventions presented in Groups I, II and III, while distinct, do not lack unity and thus should not be subject to restriction.

The common technical feature of the present inventions is a topical pharmaceutical composition comprising a lavendustin derivative and an emollient. Applicant submits respectfully that this common technical feature is patentable over U.S. Patent No. 5,990,116 to Nussbaumer ("Nussbaumer") and Kameshwari et al., *Cosmetics & Toiletries*, 114(1):45-51 (1999) ("Kameshwari"). Nussbaumer and Kameshwari each do not disclose the present common technical feature. Further, a person skilled in the art would not combine Nussbaumer and Kameshwari in such a way as to produce the present common technical feature.

In particular, Nussbaumer discloses topical pharmaceutical formulations including lavendustin derivatives. Nussbaumer, however, does not disclose the use of an emollient in such formulations or recognize that lavendustin derivatives, when applied topically, cause severe skin irritation. Kameshwari discloses the effect of various emollients on the sensory

properties of cosmetic formulations. Kameshwari, however, does not disclose the use of emollients in pharmaceutical formulations, or that emollients can decrease the skin irritant properties of pharmaceutically active compounds and, in particular, of lavendustin derivatives. Accordingly, a person skilled in the art would not combine the lavendustin derivatives of Nussbaumer with an emollient of Kameshwari to produce a topical pharmaceutical composition with the expectation that the severe skin irritant properties of lavendustin derivatives would be decreased. As the inventions presented in Groups I, II, and III do not lack unity, a search and examination of all of the presently pending claims is requested respectfully.

### **Conclusion**

Applicants believe that the foregoing constitutes a complete and full response to the Action of record. If there are any issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney.

No fee for this response is required. Nevertheless, the Commissioner is hereby authorized to charge any fees required to Deposit Account No. **19-0134** in the name of Novartis.

Respectfully submitted,

Novartis  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-9273

Date: *22nd October 2007*

  
Cozette M. McAvoy  
Attorney for Applicant  
Reg. No. 60,457